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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,266	03/27/2002	Tadao Ohno	P21324	9535

7055 7590 10/23/2006

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EXAMINER

YU, MISOOK

ART UNIT PAPER NUMBER

1642

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/890,266

Applicant(s)

OHNO ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,9,11-16,18 and 19 is/are rejected.
- 7) ☒ Claim(s) 8, 9, 17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 1 and 3-19 are pending and under prosecution.

#### ***Claim Rejections - 35 USC § 102, Maintained***

Claims 1, 3-7, 9, 11-16, 18, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. 5, 861,159 (19 January 1999).

Claim 1, and its dependent claims are drawn to a composition comprising two main components of (1) "a microparticle" comprising a fragment of solidified tumor tissues or cells, wherein the size of the fragment to allow phagocytosis, and (2) at least one isolated cytokine or cytokine-inducing agent, wherein the dependent claim 3 further limits that the composition of the base claim further comprises an adjuvant, wherein claim 4, 5, 12-16 further limit the base claim that the tumor vaccine comprises granulocyte-macrophage-colony stimulating factor (GM-CSF), interleukin- 2, or a cytokine-controlled release preparation, and claim 19 further limits that the fragment of the base claim is a tumor antigen bound to a particle. Claim 6 is drawn to vaccine composition comprising a microparticle" comprising a fragment of solidified tumor tissues or cells, wherein the size of the fragment to allow phagocytosis, and the vaccine further comprises an adjuvant in the dependent claim 7.

Applicant argues that the prior art of record uses irradiated tumor tissues or cells, which do not resemble the claimed "solidified tumor tissues or cells".

This argument has been fully considered but found unpersuasive.

The '159 patent at column 13, lines 1-10 discloses:

FIG. 2 shows the histology of immunization sites from B16F10 melanoma mixed with gelatin/chondroitin sulfate beads. C57BL6 mice were immunized subcutaneously with 1.times.10.sup.6 irradiated B16-F10 melanoma cells admixed with 1.times.10.sup.6 gelatin/chondroitin sulfate microspheres containing either nothing (control) (A,B),

Art Unit: 1642

.gamma.-IFN (C,D), or GM-CSF (E,F). FIGS. 2G and 2H show GM-CSF transfectants at 7 days and 12 days, respectively. Sites were biopsied at either 7 days (A,C,E) or 12 days (B,D,F) after immunization and stained with hematoxylin and eosin (Magnification .times.400).

The tumor vaccine used in Fig. 2 C-H are tumor vaccine comprising a microparticle comprising cells, without soluble tumor antigen from the solidified tumor tissues or cells being present in a soluble form, because the tumor cells mixed with gelatin/chondroitin sulfate beads are not soluble, i.e. they would not be in the supernatant if centrifuged at 15,000 rpm for 3 minutes (see page 19 of the instant specification).

### **Conclusion**

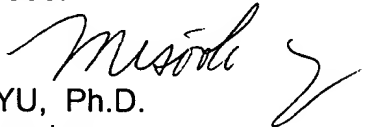
Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Art Unit: 1642

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
MISOOK YU, Ph.D.  
Primary Examiner  
Art Unit 1642